InWave

User’s Manual

InWave
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Zynex Medical
Contact Information

CUSTOMER SERVICE **1-866-940-7030**

Supplies: To order more electrodes or other accessories

Technical Support: Questions or problems with using your device

Device Return: Order a postage paid return envelope to return your device at no charge

MAIN OFFICE **1-800-495-6670**

Billing Questions: Questions regarding insurance benefits and covered benefits for Durable Medical Equipment (DME) or questions about an Explanation of Benefits form you received in the mail

FAX NUMBER **1-800-495-6695**

MAILING ADDRESS

Zynex Medical, Inc.
9990 Park Meadows Drive
Lone Tree, CO 80124-6739
USA

EMAIL **info@zynexmed.com**

WEBSITE **www.zynexmed.com**

About the InWave

The InWave is a multiple-mode stimulator which allows users a choice of treatment options. The InWave causes muscle contractions which exercise and strengthen the pelvic floor muscles.

Stress Incontinence Treatment
The output delivers electrical impulses at a frequency of 50 Hz, which produce smooth, even muscle contractions. This type of stimulation exercises and strengthens the pelvic floor muscles, which aids in the control of stress incontinence.
Stimulation can be set to 3 or 5 second duration, with a resting period of 5 or 10 seconds between contractions.
Default treatment time is 15 minutes.

Urge Incontinence Treatment
The output delivers electrical impulses at a frequency of 12.5 Hz, which produce a series of short, rapid contractions. This type of stimulation aids in the relaxation of involuntary muscle contractions which cause urge incontinence.
Stimulation can be set to 6 or 10 second duration, with a resting period of 3 or 10 seconds. Default treatment time is 20 minutes.

Mixed Incontinence Treatment
Mixed treatment modes consist of a 2, 5, or 10 minute stress treatment followed by a 2, 5, or 10 minute urge treatment. This combination of stimulation types aids in both stress and urge incontinence in the manners mentioned above.

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Safety Information

• Equipment Classification

As per the International Electrotechnical Commission standard IEC 60601-1, and the European standard EN 60601-1, Medical Electrical Equipment, General Requirements for Basic Safety and Essential Performance, the InWave is classified as follows:

- **Type BF Equipment**
  A Type BF piece of equipment is one that provides a particular degree of protection against electric shock, particularly regarding allowable leakage current. Type BF applied part is one that is floating above ground and is isolated from all other parts of the equipment.

- **Medical Device Directive (MDD) Classification**
  The InWave is a Class IIa medical device per the European Medical Device Directive.

- **Internally Powered Equipment**
  The InWave is powered by an internal, 9 VDC, MN1604, battery, so it is classified as Internally Powered Equipment.

- **Electromagnetic Compatibility**
  Conforms to IEC 60601-1-2.

- **Temperature**
  Operating temperature range: 0° - 40° C (32° - 104° F)
  Storage temperature range: -20° - 70° C (-4° - 158° F)

- **Water Ingress**
  Ordinary equipment. This device does not have protection against ingress of water.

- **Flammable Anesthetics**
  This device is not suitable for use in the presence of a flammable anesthetic mixture with air, or in the presence of a flammable anesthetic mixture with oxygen or nitrous oxide.

Safety Information

- **Mode of Operation**
  This device is suitable for continuous operation.

- ## Symbols

Safety symbols shown on the device above are defined below.

On/Standby. This symbol indicates that the labeled switch electronically cycles the DC power on and off for part of the equipment.

General Warning Sign. Follow warnings stated in the instruction manual to prevent potential hazards.

Refer to Instruction Manual/Booklet. The operator must read, understand, and follow all instructions in the accompanying document including all warnings, cautions, and precautions before using this medical device.

Type BF Equipment. This symbol indicates that the patient applied parts (electrodes) are Type BF (floating from ground) offering the user a specific level of safety.

Waste Electrical and Electronic Equipment (WEEE). This product may contain substances known to be hazardous to the environment or to human health. It should be disposed of properly (for example, at your local waste collection administration or recycling plant) and in accordance with local ordinances.

• Service and Calibration

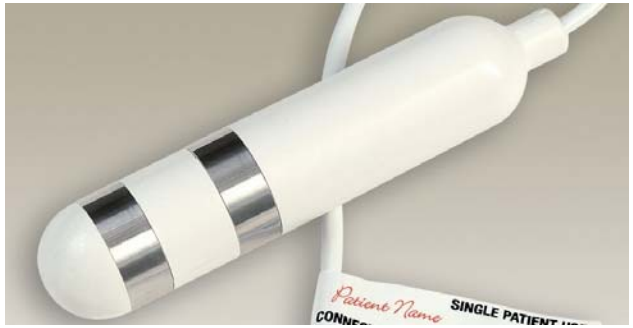
- Do not remove the cover. There are no user serviceable parts. Refer all service to authorized personnel. No modification of the equipment is allowed.

- No preventative inspections are required. Factory testing and calibration ensure equipment accuracy and response. Contact Zynex Medical for factory re-calibration if necessary.

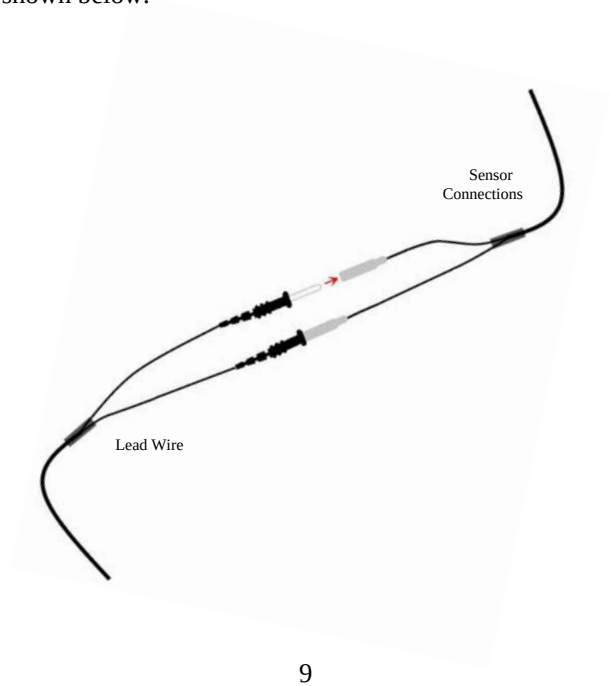
InWave
Sensor and Lead Wire Setup

Step 1 Open the sensor package and remove the sensor. Remove the electrode wire from the packaging, and unbundle the wire.

Note: Only Zynex Medical sensors are approved for use with the InWave. P/N 400015 are provided standard.



Step 2 Insert the lead wire pin connectors into the sensor connectors as shown below.



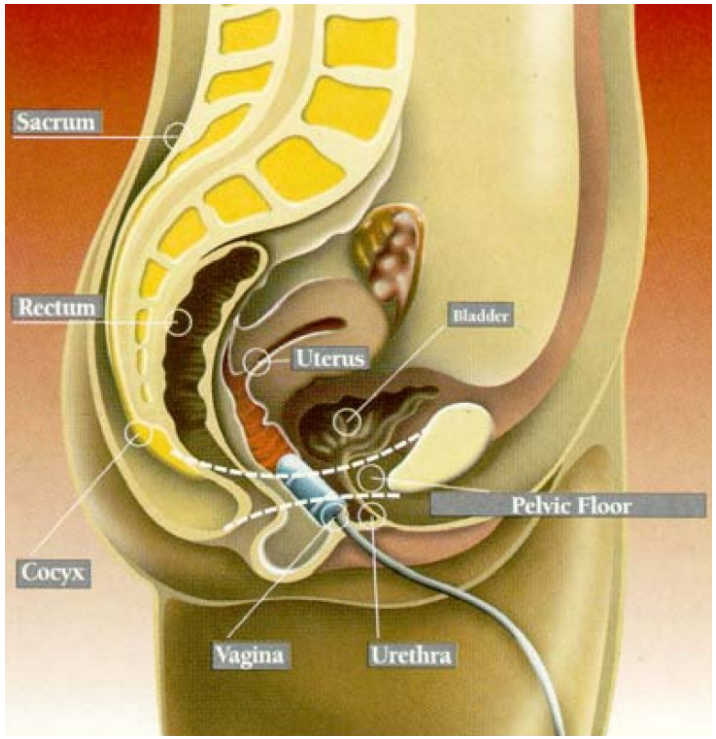
InWave

Electrode and Lead Wire Setup (continued)

Step 3 Insert vaginal sensor as shown below. If needed, a small amount of water-based lubricant can be applied to the tip of the sensor to aid in insertion. Initial placement of the vaginal sensor and selection of the treatment program should be performed under the guidance of a physician. **Note:** Overuse of a lubricant can cause lack of stimulation, and lead to ineffective treatment. In order to avoid treatment interruption, it may be necessary to empty the bladder and bowels before starting a treatment session.

See the directions included with the sensor for further information.

Note: The vaginal sensors are for **single patient use only**.

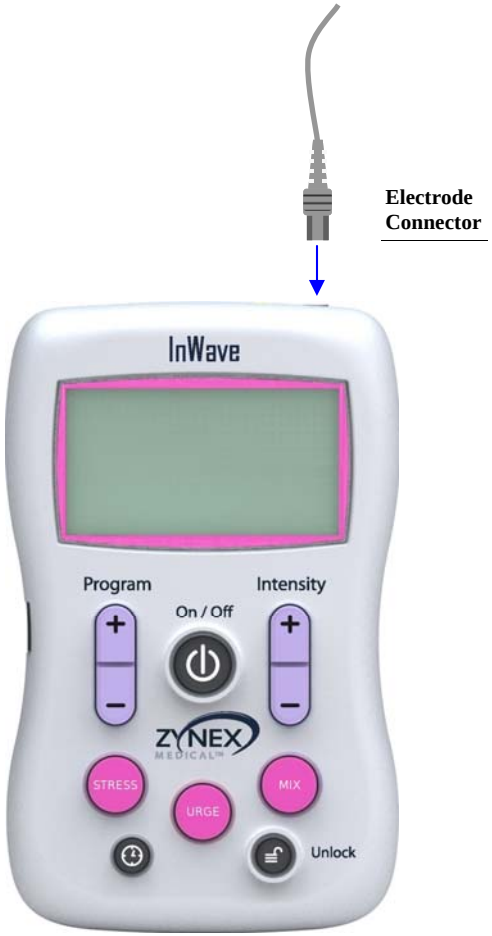


InWave

Electrode and Lead Wire Setup (continued)

Step 4 Plug the lead wire into the top of the device.

Step 5 Proceed to page 16 to start treatment or page 12 to program device.



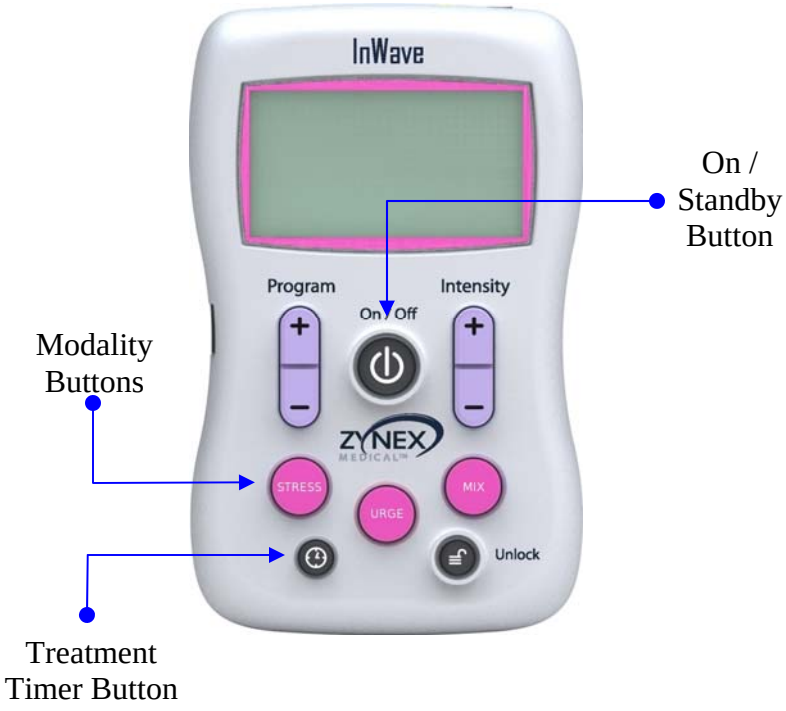
InWave

Device Programming Instructions

Turn device on by pressing the black On/Standby button

1. Select the desired Modality by pressing the “STRESS”, “URGE”, or “MIX” button once.
2. Press the “+” or “-” portions of the Program button until the arrow on the LCD is next to the desired program.
3. Press the Treatment Timer button until the desired treatment time is set on the screen.

The InWave is now ready to use.



InWave
Preprogrammed Modes

Stress Incontinence Treatment (50 Hz Frequency, 200 µSecond Pulse Width)

Program	Description
5/10	The output signal ramps up to the level set by the user over a period of 1 second. The output stays on for the remainder of the 5 second on time, then ramps down to zero over a period of 1 second. The output stays off for the remainder of the 10 second off time. This cycle repeats for the duration of the treatment time. (Default is 15 minutes.)
3/10	The output signal ramps up to the level set by the user over a period of 1 second. The output stays on for the remainder of the 3 second on time, then ramps down to zero over a period of 1 second. The output stays off for the remainder of the 10 second off time. This cycle repeats for the duration of the treatment time. (Default is 15 minutes.)
5/5	The output signal ramps up to the level set by the user over a period of 1 second. The output stays on for the remainder of the 5 second on time, then ramps down to zero over a period of 1 second. The output stays off for the remainder of the 5 second off time. This cycle repeats for the duration of the treatment time. (Default is 15 minutes.)

Urge Incontinence Treatment (12.5 Hz Frequency, 600 µSecond Pulse Width)

Program	Description
10/3	The output signal ramps up to the level set by the user over a period of 1 second. The output stays on for the remainder of the 10 second on time, then ramps down to zero over a period of 0.5 seconds. The output stays off for the remainder of the 3 second off time. This cycle repeats for the duration of the treatment time. (Default is 20 minutes.)
6/3	The output signal ramps up to the level set by the user over a period of 1 second. The output stays on for the remainder of the 6 second on time, then ramps down to zero over a period of 0.5 seconds. The output stays off for the remainder of the 3 second off time. This cycle repeats for the duration of the treatment time. (Default is 20 minutes.)
10/10	The output signal ramps up to the level set by the user over a period of 1 second. The output stays on for the remainder of the 6 second on time, then ramps down to zero over a period of 0.5 seconds. The output stays off for the remainder of the 3 second off time. This cycle repeats for the duration of the treatment time. (Default is 20 minutes.)

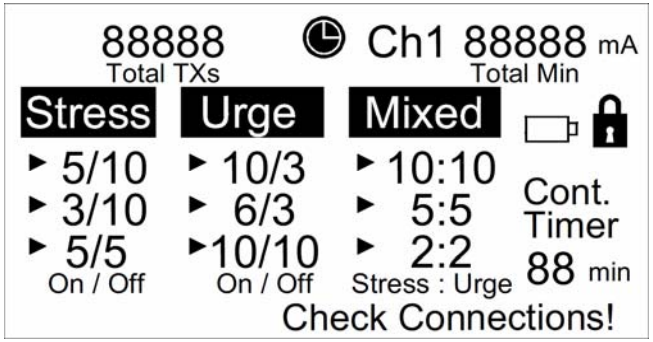
Mixed Incontinence Treatment

Program	Description
10:10	A 10 minute “5/10” Stress program is run, followed by a 10 minute “10/3” Urge program. This cycle repeats for the duration of the treatment time. Default treatment time is 20 minutes.
5:5	A 5 minute “5/10” Stress program is run, followed by a 5 minute “10/3” Urge program. This cycle repeats for the duration of the treatment time. Default treatment time is 20 minutes.
2:2	A 2 minute “5/10” Stress program is run, followed by a 2 minute “10/3” Urge program. This cycle repeats for the duration of the treatment time. Default treatment time is 20 minutes.

The InWave should be used daily for 15 to 20 minutes per session, for 1 to 3 months, or as directed by a physician.

InWave

Device Controls



Display

Attach Lead Wire Here

Lead Wire Connector

Turns Unit On/Off

On/Standby Button

Cycles Through Programs

Program Select Button

Adjusts Treatment Intensity

Up and Down Button

Unlocks Control Buttons

Unlock Button

STRESS, URGE, MIX

Modality Buttons

Adjusts Treatment Times

Treatment Timer Button

InWave
Device Operating Instructions

Start Treatment:

Before starting treatment, the sensor must be inserted and the lead wire must be connected to the InWave. See pages 9-11 for instructions.

1. Turn the InWave on by pressing the On/Standby button once, and set the desired program using the Modality and Program buttons.
2. Increase the stimulation level by pressing the upper portion of the Intensity button until a strong but comfortable stimulation level is felt.

   NOTE: Output increases in 1/2 mA increments up to the 4 mA level, then increases in increments of 1 mA.
3. Once the desired level of stimulation is set, the InWave will automatically shut off after the preset treatment time (shown on the display.) If the Treatment Timer has been set to, "No Timer," then the InWave will need to be shut off manually. *Refer to Programming Instructions on page 12 to adjust the Treatment Timer.*
4. To turn off the InWave manually, press the On/Standby button.

   Note: If "Check Connections!" message is displayed on the screen, see "Display Alerts" below.

During Treatment:

IMPORTANT: *Button controls lock after 20 seconds of inactivity. To unlock button controls, press the Unlock button.*

Increase Intensity:

To increase the intensity, press the upper potion of the Intensity button until the desired level of stimulation is felt.

Decrease Intensity:

To decrease the intensity, press the lower portion of the Intensity button until the desired level of stimulation is felt.

Display Alerts:

Check Connections: The lead wire and/or the sensor may not be attached properly. Check all connections and try again (see page 23). If the problem persists, call Technical Support (see page 4).

Low Battery: Replace the battery immediately.

Locked: The stimulation level and mode cannot be changed until the Unlock button is pressed.

InWave

Indications for Use

Stress Incontinence Mode

Please read the InWave User's Manual before using the InWave pelvic muscle stimulator.

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. This device should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Indications

- The Zynex Medical InWave is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women.

Contraindications

- This InWave should not be used in the presence of the following:
  - -Where there is a tendency to hemorrhage following acute trauma or fracture.
  - -Following recent surgical procedures when muscle contraction may disrupt the healing process.
  - -Over the menstruating or pregnant uterus.
  - -Over areas of the skin which lack normal sensation.
  - -Irregular menstrual cycles.
  - -Urinary or vaginal infection.
  - -History of urinary retention or current symptoms.

Warnings

- The long-term effects of chronic electrical stimulation are unknown.
- Safety has not been established for the use of the InWave during pregnancy.
- The device is capable of generating currents and voltages in excess of 10 mA RMS and 10 V RMS, respectively. A yellow LED indicator is provided next to the lead wire connector to show that the unit is delivering energy for any non-zero value of stimulation output (0.5 to 80 mA).
- Discontinue use of this device in the event of pain or bleeding.
- Do not use this device in water.
- Do not insert the lead wires into a mains power supply.

InWave

Precautions and Adverse Reactions

Stress Incontinence Mode

Precautions

- Stimulation settings should be based on the guidance of the prescribing practitioner.
- This device should be kept out of the reach of children.
- This device should only be used with the leads and vaginal sensor recommended for use by the manufacturer.
- This device should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at risk of injury.
- Caution should be exercised when this device is used by patients with pacemakers and heart rhythm problems.
- Do not use this device while under the influence of drugs or alcohol.
- Do not insert or remove the vaginal sensor while the device is ON.
- Do not use this device while in the close proximity of wireless devices.
- Use this device only as directed.
- Do not immerse the unit in water or any other liquid.
- The vaginal sensor should not remain inserted in the vagina when the unit is not in use.
- This device should not be used while sleeping or when anything else is in the vagina, such as a diaphragm or tampon.

Adverse Reactions

- Skin irritation and electrode burns are potential adverse reactions.

Safety References

Zynex Medical, Inc. is only responsible for the safety, reliability and function of the device when repairs and adjustments have been made by persons authorized by Zynex Medical, Inc., and the device is used in accordance with the user's manual. Repairs and technical safety tests shall only be performed by authorized personnel.

InWave

Indications for Use

Urge Incontinence Mode

Please read the InWave User's Manual before using the InWave pelvic muscle stimulator.

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. This device should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Indications

- The Zynex Medical InWave is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women.

Contraindications

- This InWave should not be used in the presence of the following:
  - -Where there is a tendency to hemorrhage following acute trauma or fracture.
  - -Following recent surgical procedures when muscle contraction may disrupt the healing process.
  - -Over the menstruating or pregnant uterus.
  - -Over areas of the skin which lack normal sensation.
  - -Irregular menstrual cycles.
  - -Urinary or vaginal infection.
  - -History of urinary retention or current symptoms.

Warnings

- The long-term effects of chronic electrical stimulation are unknown.
- Safety has not been established for the use of the InWave during pregnancy.
- The device is capable of generating currents and voltages in excess of 10 mA RMS and 10 V RMS, respectively. A yellow LED indicator is provided next to the lead wire connector to show that the unit is delivering energy for any non-zero value of stimulation output (0.5 to 80 mA).
- Discontinue use of this device in the event of pain or bleeding.
- Do not use this device in water.
- Do not insert the lead wires into a mains power supply.

InWave

Precautions and Adverse Reactions

Urge Incontinence Mode

Precautions

- Stimulation settings should be based on the guidance of the prescribing practitioner.
- This device should be kept out of the reach of children.
- This device should only be used with the leads and vaginal sensor recommended for use by the manufacturer.
- This device should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at risk of injury.
- Caution should be exercised when this device is used by patients with pacemakers and heart rhythm problems.
- Do not use this device while under the influence of drugs or alcohol.
- Do not insert or remove the vaginal sensor while the device is ON.
- Do not use this device while in the close proximity of wireless devices.
- Use this device only as directed.
- Do not immerse the unit in water or any other liquid.
- The vaginal sensor should not remain inserted in the vagina when the unit is not in use.
- This device should not be used while sleeping or when anything else is in the vagina, such as a diaphragm or tampon.

Adverse Reactions

- Skin irritation and electrode burns are potential adverse reactions.

Safety References

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InWave

Indications for Use

Mixed Incontinence Mode

Please read the InWave User's Manual before using the InWave pelvic muscle stimulator.

CAUTION: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. This device should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Indications

- The Zynex Medical InWave is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women.

Contraindications

- This InWave should not be used in the presence of the following:
  - -Where there is a tendency to hemorrhage following acute trauma or fracture.
  - -Following recent surgical procedures when muscle contraction may disrupt the healing process.
  - -Over the menstruating or pregnant uterus.
  - -Over areas of the skin which lack normal sensation.
  - -Irregular menstrual cycles.
  - -Urinary or vaginal infection.
  - -History of urinary retention or current symptoms.

Warnings

- The long-term effects of chronic electrical stimulation are unknown.
- Safety has not been established for the use of the InWave during pregnancy.
- The device is capable of generating currents and voltages in excess of 10 mA RMS and 10 V RMS, respectively. A yellow LED indicator is provided next to the lead wire connector to show that the unit is delivering energy for any non-zero value of stimulation output (0.5 to 80 mA).
- Discontinue use of this device in the event of pain or bleeding.
- Do not use this device in water.
- Do not insert the lead wires into a mains power supply.

InWave

Precautions and Adverse Reactions

Mixed Incontinence Mode

Precautions

- Stimulation settings should be based on the guidance of the prescribing practitioner.
- This device should be kept out of the reach of children.
- This device should only be used with the leads and vaginal sensor recommended for use by the manufacturer.
- This device should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at risk of injury.
- Caution should be exercised when this device is used by patients with pacemakers and heart rhythm problems.
- Do not use this device while under the influence of drugs or alcohol.
- Do not insert or remove the vaginal sensor while the device is ON.
- Do not use this device while in the close proximity of wireless devices.
- Use this device only as directed.
- Do not immerse the unit in water or any other liquid.
- The vaginal sensor should not remain inserted in the vagina when the unit is not in use.
- This device should not be used while sleeping or when anything else is in the vagina, such as a diaphragm or tampon.

Adverse Reactions

- Skin irritation and electrode burns are potential adverse reactions.

Safety References

Zynex Medical, Inc. is only responsible for the safety, reliability and function of the device when repairs and adjustments have been made by persons authorized by Zynex Medical, Inc., and the device is used in accordance with the user's manual. Repairs and technical safety tests shall only be performed by authorized personnel.

Troubleshooting	
Problem	**Solution**
Unit stays on even after treatment ends.	Hold Off button down for 2 seconds to shut unit off. Otherwise unit will shut off automatically after 5 minutes of no stimulation. Alternatively you can start a new treatment session after the last one ends.
Cannot increase level from its current setting.	Press and release Unlock button to unlock this safety feature. Then increase stimulation to the desired level of intensity. Intensity level is always locked after 20 seconds of key press inactivity.
Display shows “Check Connections” (Electrode alarm).	Check to see that the sensor is properly inserted. (Remove and re-insert the sensor if necessary to establish a better electrical contact.) Verify that the sensor is correctly connected to the lead wire and that the lead wire is correctly connected to the InWave. Connect the bare metal pins of the lead wire together to short-circuit the output. If the electrode alarm ceases the problem is with the sensor connection integrity. Removing and re-inserting the sensor may establish a better electrical contact.

InWave
Specifications and Accessories

Stress Incontinence Mode

Amplitude:	0-80 mA
Frequency:	50 Hz
Pulse Width:	200 µseconds
Stress Modes:	5/10, 3/10, 5/5
On Time:	3 or 5 seconds
Off Time:	5 or 10 seconds
Ramp Up Time:	1 second
Ramp Down Time:	1 second
Waveforms:	Symmetrical biphasic

Urge Incontinence Mode

Amplitude:	0-80 mA
Frequency:	12.5 Hz
Pulse Width:	600 µseconds
Urge Modes:	10/3, 6/3, 10/10
On Time:	6 or 10 seconds
Off Time:	3 or 10 seconds
Ramp Up Time:	1 second
Ramp Down Time:	0.5 seconds
Waveform:	Symmetrical biphasic

Mixed Incontinence Mode

Amplitude:	0-80 mA
Frequency:	12.5 Hz and 50 Hz
Pulse Width:	200 µseconds and 600 µseconds
Mix Modes:	10:10, 5:5, 2:2
On-Time:	3, 5, 6, or 10 seconds
Off-Time:	3, 5, or 10 seconds
Ramp Up:	1 second
Ramp Down:	0.5 or 1 second
Waveforms:	Symmetrical biphasic

Other Specifications

Treatment timer:	5 to 25 minutes, in 5 minute increments.
Compliance meter:	Records total usage time in minutes and number of times used.
Dimensions:	2.9 x 4.6 x 1.0 in.
Weight:	5.8 oz. including battery
Warranty:	5 year manufacturer's warranty on materials and workmanship. Accessories excluded.

Accessories

Lead wire:	104204, lead wire, gray.
Sensor:	400015, vaginal sensor.
Battery:	130010, battery, 9 Volt, alkaline, MN1604.

InWave
Sensor, Batteries, and Cleaning

Sensor Use

The InWave is intended to be used with a re-usable vaginal sensor. Before and after each use, clean the sensor with mild soap and water, and dry the sensor. Store the sensor in a safe location when not in use.

Follow directions of the prescribing physician.

Note: The vaginal sensors are for **single patient use only**.

Battery Power

One 9 Volt alkaline battery is used to power the InWave. The battery compartment on the back of the device opens by sliding the cover downwards. Rechargeable batteries are not recommended since they have only a short usage time and cannot be charged while in the InWave.

Battery replacement is indicated by the battery icon in the display. Replace with a new 9 Volt alkaline battery.

The InWave operates normally even if the 9 Volt battery is inserted with reverse polarity.

Please dispose of used batteries properly.

Device Cleaning

The InWave case and display window can be cleaned by lightly applying mild soap to a damp soft cloth or paper towel and using it to wipe the surfaces clean. Allow the unit to dry thoroughly before using. Do not spray cleaning solutions directly onto the unit, or immerse it in water or other liquids.

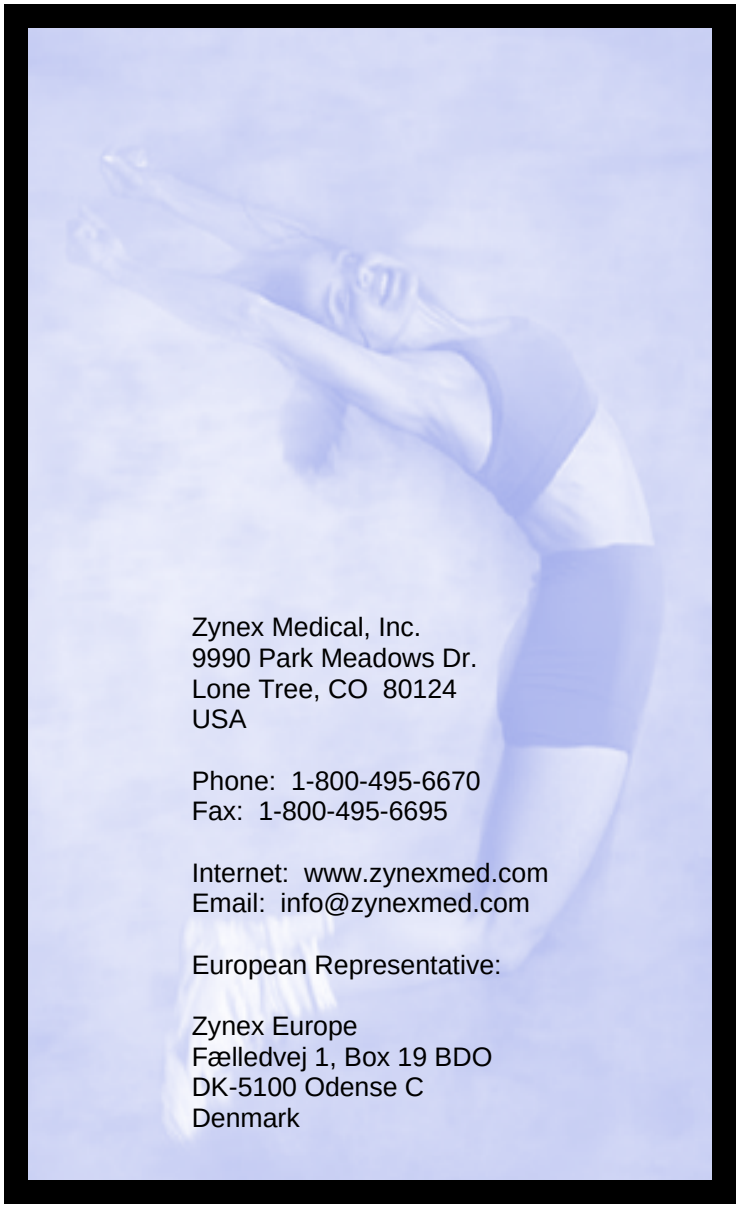
InWave
Warranty Information

The InWave device is warranted to be free from defects in material, workmanship, and structural integrity when subjected to normal domestic use and service for five years after the original purchase.

During that time, Zynex Medical, Inc will repair or replace, at its sole discretion, the InWave device that has been used in a standard manner. This warranty does not cover misuse or use contrary to the operating instructions supplied.

Warranty obligations are limited to replacement or repair of defective parts and components, at the option of Zynex Medical, Inc. This Warranty is only valid for the original purchaser of this product and will not be honored if the product ownership is transferred or is resold.

To obtain warranty service, please contact Technical Support at the number listed on page 4 of this manual.



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